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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,454	01/05/2004	Jean-Paul Renard	045636-5058	9282
9629 7590 04/30/2008 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004				
EXAMINER BERTOGGIO, VALARIE E				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/089,454

Applicant(s)

RENARD ET AL.

Examiner

Valarie Bertoglio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2007 and 05 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on N/A is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/003)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This application was filed January 5, 2004, is a 371 national stage filing of PCT/FR00/02698, filed September 29, 2000, which claims benefit to foreign application 99/12287 filed October 1, 1999 in France.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/05/2007 has been entered.

Claims 1-12 are cancelled. Claim 13 is amended. Claim 25 is added. Claims 13-25 are pending and under consideration in the instant office action.

Oath/Declaration

A new oath was received 12/05/2007.

Specification

The objection to the specification is withdrawn in light of Applicant's amendment to the specification dated 12/05/2007.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-25 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 13 remains vague and unclear as to what is "reconstituted", and incomplete because while the preamble indicates a method for the reconstitution of an embryo the method steps only involve steps of obtaining a nuclear transfer unit. The preamble implies that the donor is transferred to recipient cytoplasm, and dependent claims set forth potential specific methodology (claims 19-22) however an embryo is not formed by merely placing a donor nucleus into a cytoplasmic fraction as is the final step recited in claim 13. What is obtained from the method as claimed, is an oocyte comprising a treated donor nucleus. No activation has occurred such that a zygote, then embryo, is formed. It is noted that the specification at page 7, lines 9-10 states that activation is necessary. However, at page 8, lines 8-10, it is stated that no further activation is required. Clarification of the methodology is requested. Claims 14-25 depend from claim 13. Applicant argues that the nuclear transfer unit is competent to divide. However, without an oocyte activation step, it is not clear division will occur or that an embryo is obtained.

The aspect of the rejection with respect to the recitation of "controlled proteolysis" is withdrawn in light of Applicant's amendment to the claim.

Claim 13 recites the limitation "said nucleus" in line 7. There is insufficient antecedent basis for this limitation in the claim. It is not clear if the limitation is referring to the treated nucleus made by step (i) or some other nucleus. The claim would read clearly if it recited "said treated nucleus".

Claim 25 is unclear because it adds a method step to a parent claim that recites closed methodology. Parent claim 13 is a method that consists of step (i) and (ii). However, claim 25 adds a step to the closed method.

MPEP 2111.03 recites "A claim which depends from a claim which "consists of" the recited elements or steps cannot add an element or step. When the phrase "consists of" appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause; other elements are not excluded from the claim as a whole. *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986)."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351 (a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-15, 17-19 remain rejected and newly added claim 25 is rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. (US Patent 6,753,457 B2). The rejection is maintained for reasons of record set forth at page 6 of the office action dated 10/10/2006.

Applicant argues that Wang teaches additional method steps that are not required by the claims and that the claims are written with closed language "consisting of". This argument is not persuasive because the additional methodology, treatment of nuclei with egg extract or CSF to induce swelling, taught by Wang is encompassed by step (i)(b). Step (i)(b) of claim 13 recites "induction of isomorphic swelling of said nucleus". This step is broad and encompasses any method of inducing swelling,

including the activation and swelling that is induced using various methods of Wangh. Wangh states "“Activation” of a non-dividing cell nucleus refers to one or more of the following activities: nuclear swelling, nucleic acid replication, and nuclear entrance into mitosis thereby producing metaphase chromosomes (arrested metaphase chromosomes or replicating chromosomes)”(col.2, lines 27-30). Wangh also states that “Examples of agents which enhance nuclear activation caused by an activating agent include CSF extract, purified components thereof, and proteases.” (col. 2, lines 60-65).

Thus, the claims broadly encompass any method causing an induction of swelling, which is taught by Wangh. The instant specification teaches induction of swelling using polyanionic compounds, however, the claims are not so-limited and do not exclude the methodology of Wangh.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-15, 17-24 remain rejected and newly added claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wangh et al. (US Patent 6,753,457 B2). The rejection is maintained for reasons of record set forth at pages 7-8 of the office action dated 10/10/2006.

Applicant argues that Wang teaches additional method steps that are not required by the claims and that Wangh fails to teach reconstitution of non-human mammalian embryos. Applicant argues that the additional methodology of Wangh that is not recited in the claims is necessary to carryout the invention disclosed in Wangh and thus, one of skill in the art would not be motivated to remove those steps.

In response, as set forth above, the additional methodology of Wangh arc methods steps encompassed by the instantly claimed step if 'inducing swelling' of the nucleus. Thus, the teachings of Wangh are not outside the breadth of the claims. As set forth at pages 7-8 of the office action dated 10/10/2006, Wangh *et al.* teach that any animal, in particular mammals, can be generated using the method of nuclear transfer and specifically reduce to practice the use of microinjection. However, Wangh *et al.* fails to teach other methods of cell fusion or specific species of mammals such as cows, pigs and sheep. At the time of filing methods of practicing insertion of the donor cell into the recipient oocyte were performed by various methods and devices conventional to a particular laboratory. Similarly, at the time of filing the specific mammals that were the subject of research and being generated by nuclear transfer were sheep, cows and pigs. The present disclosure indicates that any method for nuclear transfer known in the art can be used and would adapted to the methods of treating the nuclear donor cell as instantly claimed, therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the methods of Wangh *et al.* generally disclosed for generating ungulates such as cows, pigs and sheep, as well as use the methods established to most effectively generate the NT unit for each of these mammals. One having ordinary skill in the art would have been motivated to substitute for microinjection other methods such as electrofusion because of the success in a particular species of animal, ease over microinjection or availability of equipment in a given laboratory. Similarly, the generation of a particular mammal would be obvious and dependent on an individuals research model. The instant disclosure relies of the methods of nuclear transfer known in the art at the time of filing,

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so there would have been a reasonable expectation of success given the results of Wangh *et al.* and those generally known in the art for the use of other NT transfer methods and for the production of other mammals.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio, Ph.D./
Primary Examiner
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